

Our Case No. 10546/6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John W. Wong et al.)
) Examiner: Mendoza, Michael G.
U.S. Patent Application Serial No.: 09/424,431) Group Art Unit No. 3731
Filed: March 16, 2000))
For: METHOD AND APPARATUS FOR DELIVERING RADIATION THERAPY DURING SUSPENDED VENTILATION))))

APPEAL BRIEF

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Appeal is in response to the Final Office Action mailed March 8, 2005¹.

I. REAL PARTY IN INTEREST

It is believed that William Beaumont Hospital is a real party of interest in this Appeal pursuant to 1) a recorded assignment of the above-identified application to

¹ Appellants filed a Notice of Appeal on July 8, 2005 concurrently with the filing of a Petition for a one month extension of time. Accordingly, the Notice of Appeal was timely filed. Since the present Appeal Brief is being filed within two months of the filing of the Notice of Appeal, the present Appeal Brief is timely filed.

William Beaumont Hospital executed by all of the inventors of record, John W. Wong, David A. Jaffray, Michael B. Sharpe and John R. Musselwhite.

It is also believed that Elekta Oncology Systems Ltd. of Crawley, West Sussex, United Kingdom is a real party of interest in this Appeal pursuant to a license entered into between William Beaumont Hospital and Elekta Oncology Systems Ltd. regarding the above-identified application.

II. RELATED APPEALS AND INTERFERENCES

The undersigned, John C. Freeman, is not aware of any other appeals, interferences or other judicial proceedings that may be related to, would directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

III. STATUS OF CLAIMS

The status of the claims is as follows:

Claims 1-14 and 16-22 are canceled.

Claim 32 is finally rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter.

Claims 15, 29-31 and 33 are finally rejected under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 5,485,833 to Dietz, U.S. Patent No. 5,067,494 to Rienmueller et al. and U.S. Patent No. 6,436,127 to Anderson et al.

Claims 23-26 and 34-36 are finally rejected under 35 U.S.C. § 103(a) as being obvious in view of Dietz, Rienmueller et al., Anderson et al. and U.S. Patent No.

4,815,459 to Beran.

Claims 27, 28, 37 and 38 are finally rejected under 35 U.S.C. § 103(a) as being obvious in view of Dietz, Rienmueller et al., Anderson et al. and U.S. Patent No. 4,752,064 to Voss.

The above-mentioned rejections of claims 15 and 23-38 are the subject of this Appeal.

IV. STATUS OF AMENDMENTS

Appellants filed an Amendment on May 9, 2005 in response to the Final Office Action mailed on March 8, 2005. The Amendment of May 9, 2005 was entered in the Advisory Action mailed on June 24, 2005. No Amendment or Response has been filed subsequent to the Amendment of May 9, 2005 and prior to the filing of the present Appeal Brief regarding the Final Office Action mailed on March 8, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

An understanding of the inventions of independent claims 15 and 33 can be made upon a review of several embodiments of the inventions shown in Figs. 1-3 and 5-6 of the specification. Note that in the description to follow, like elements will employ identical identification numerals.

In one embodiment shown in Fig. 1, an active breathing control apparatus 10 utilizes a ventilator assembly 13. (p. 9, II. 5-6). The apparatus 10 has two "scissors" valves 14 and 16 to monitor and control inhalation and exhalation independently. (p. 9, II. 7-8). During normal operation, one of the valves 14 or 16 is always closed while the

other is open. (p. 9, II. 8-10). The scissors valves 14 and 16 are interfaced to a personal computer (p. 9, II. 10-12). The signals from the valves 14 and 16 are processed to display the changing lung volume during the breathing cycle. (p. 9, II. 12-13).

As shown in Figs. 1-3, a patient 12 is interconnected to the modified ventilator assembly 13 through a subassembly 18 which includes a t-connector 19 which includes one-way valves 20 and 21, a pneumotach 22 and a mouthpiece 23. (p. 9, II. 16-19).

The valves 14 and 16 as well as the pneumotach 22 are connected to a computer 28 which selectively drives each element according to a selected operations program. (p. 10, II. 1-3).

The approximate position of the ventilator assembly 13 relative to a supine patient 12 is shown in Fig. 2. (p. 10, II. 4-6). A mirror 30 may be provided at an angle for viewing by the patient 12. (p. 10, II. 6-7). A monitor 32 may be provided outside of the treatment room for the operator, while a smaller monitor 34 (or LCD) may be attached to the mirror 64 for viewing by the patient. (Fig. 2, p. 10, II. 8-10). The monitors 32 and 34 continuously display the cyclical lung volume trace and the target respiration level while the supine patient is breathing. (p. 10, II. 10-12). Each of the monitors 32 and 34 is operatively associated with the computer 28. (p. 10, II. 13-14). An abort switch 36 may also be provided for operation by the patient 12 to turn off the radiation machine and open the valve 14 in the event of discomfort. (p. 10, II. 14-16).

A second embodiment of the present invention is shown in Figs. 5 and 6. The embodiment includes a control apparatus 50, a single valve 52 and a pneumotach 54 to monitor and control inhalation and exhalation. (p. 10, I. 23 – p. 11, I. 2). The valve 52

and the pneumotach 54 are connected to a computer 55 via lines 56 and 58. (p. 10, II. 2-4).

When the apparatus 50 in operatively associated with a supine patient 12', a mouthpiece 13' is used for ventilation. (p. 11, II. 8-9). A mirror 64 may be provided at an angle for viewing by the patient 12'. (p. 11, II. 10-11). A monitor 66 is preferably provided outside of the treatment room for the operator, while a smaller personal monitor (or LCD) 68 may be attached to the mirror 64 for viewing by the patient. (Fig. 6, p. 11, II. 11-14). Both the monitor 66 and the personal monitor 68 are operatively associated with the computer 55. (p. 11, II. 14-15). An abort switch 70 may also be provided for operation by the patient 12' to turn off the radiation machine and open the valve 52 in the event of discomfort. (p. 11, II. 15-17).

Operation of the apparatuses of Figs. 1-3 and 5-6 is similar. In particular, the patient lies in a supine position on a rigid surface table-top. (p. 12, II. 3-4). One end of the bi-directional pneumotachnometer is connected to the patient via the mouthpiece while the other is connected to the scissors valve (one or two valves, depending on the embodiment) which controls airflow. (p. 12, II. 5-7).

The output of the pneumotachnometer is interfaced with a Pentium class PC. (p. 12, II. 15-16). The flow signal is processed to calculate the changing lung volume during breathing in real-time. (p. 12, II. 16-18). Operation of the scissor valve(s) is done under computer control. (p. 12, II. 18-19).

During an initial training session using the apparatuses 10, 50 of Figs. 1-3 and 5-6, the period of active breath hold that can be comfortably maintained by each individual patient is determined. (p. 13, II. 16-18). The period is used for subsequent CT scanning

and treatment, but is adjusted as necessary. (p. 13, II. 18-19). When the supine patient breathes in and out through the apparatuses of Figs. 1-3 and 5-6, the cyclical lung volume trace and the target level is displayed continuously on a monitor for the user outside of the treatment room. (p. 13, II. 19-22). Inside the treatment room, the patient is shown a similar display and the countdown of the breathhold period via an angled mirror. (p. 13, II. 22-24). The patient may also be provided with an "abort" switch to turn off the radiation machine and open the valve of the apparatus in case of discomfort. (p. 13, I. 24 – p. 14, I. 2).

A method of using the devices of FIGS. 1-3 and 5-6 is illustrated by the flow chart of Fig. 7. In a first step 100, a specific air flow direction and lung volume are identified. (p. 14, II. 9-10). This identification is conducted with CT scans taken at different phases of suspended ventilation. (p. 14, II. 10-11).

In a second step 200, patient ventilation is suspended at the specific air flow direction and lung volume. (p. 14, II. 12-13). Ventilation suspension is accomplished by closing the valves. (p. 14, II. 13-14). Radiation therapy is administered during suspension of patient ventilation per step 300. (p. 14, II. 16-17).

There are no means-plus-function terms or step-plus-function terms in independent claims 15 and 33 and dependent claims 23, 27-30, 32, 34, 37 and 38, which are argued separately below in Section VII.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are four grounds of rejection presented for review:

1) whether claim 32 is directed to non-statutory subject matter;

- 2) whether claims 15, 29-31 and 33 are obvious in view of the combination of Dietz, Rienmueller et al. and Anderson et al.;
- 3) whether claims 23-26 and 34-36 are obvious in view of the combination of Dietz, Rienmueller et al., Anderson et al. and Beran; and
- 4) whether claims 27, 28, 37 and 38 are obvious in view of the combination of Dietz, Rienmueller et al., Anderson et al. and Voss.

VII. ARGUMENT

A. 35 U.S.C. § 101

Claim 32 was finally rejected in the Final Office Action of March 8, 2005 (hereinafter "the Final Office Action") under 35 U.S.C. §101 as being directed to nonstatutory subject matter. In particular, claim 32 was rejected for reciting the term "mouth." Appellants traverse the rejection in that claim 32 was amended in Appellants' Amendment after Final filed on May 9, 2005 so that the word "mouth" was replaced by "mouthpiece." Since the May 9, 2005 Amendment was entered per the Advisory Action mailed on June 24, 2005 and claim 32 does not refer to a human being, the rejection is improper and should be withdrawn.

B. <u>35 U.S.C. § 103(a)</u>

1. Dietz, Rienmueller et al. and Anderson et al.

a. Claim 15

Claim 15 was finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al. and Anderson et al. Appellants

traverse the rejection for several reasons. First, Anderson et al. is directed to nonanalogous art. The test for nonanalogous art is as follows:

The determination that a reference is from nonanalogous art is therefore two-fold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. In re Deminski, 796 F.2d 436, 230 U.S.P.Q. 313 (Fed. Cir. 1986) citing In re Wood, 559 F.2d 1032, 1036, 202 U.S.P.Q. 171, 174 (C.C.P.A. 1979).

Upon applying the first prong of the test, one sees that Anderson et al. is not within the Appellants' field of endeavor. Appellants' claimed invention is in the field of methods and apparatuses for delivering radiation therapy during suspended ventilation. The Final Office Action disputes this and asserts that Appellants' claimed invention is in the more general field of delivering radiation therapy. This assertion is contrary to Appellants' own teaching as evidenced by reviewing 1) the "Field of the Invention" section of Appellants' Specification at page 1, lines 5-8 and 2) the preamble of claim 15 which recites "[a]n apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation." In contrast, Anderson et al. discloses a phototherapeutic treatment for psoriasis that does not in any way include suspending ventilation of a patient. Instead, Anderson et al.'s patient 10 breathes normally and does not have his or her breathing suspended. The Final Office Action has not disputed the fact that Anderson et al. does not suspend ventilation. Indeed, page 2 of the Final Office Action states that Dietz is recited to teach ventilation suspension. Thus, Anderson et al. is not within Appellants' field of endeavor - delivering radiation therapy during suspended ventilation.

Besides not being within the Appellants' field of endeavor, it is clear that

Anderson et al. is not reasonably pertinent to the particular problem with which

Appellants were involved. As stated on page 3 of Appellants' Specification, the problem

of organ and tumor movement during radiotherapy due to motion of the lungs and

diaphragm is the concern of Appellants' claimed invention.

It is clear that Anderson et al. does not address Appellants' problem. Instead, Anderson et al. regards applying phototherapy to the skin of a patient 10 in a sufficient manner so as to achieve clearing up the psoriasis without causing painful sunburn-like reactions. (Col. 2, II. 9-10). While Anderson et al. does disclose using either a table 12 designed to have a patient remain steady while standing (Col. 9, II. 28-31) or a table designed to reduce patient movement while lying down (Col. 9, II. 31-34), nowhere does Anderson et al. disclose or suggest that lung or diaphragm movement of the patient 10 hinders the ability to determine the proper phototherapy to the skin of the patient 10. It is noted that the Final Office Action and the Advisory Action mailed on June 24, 2005 have not disputed that Anderson et al. does not address Appellants' problem.

Assuming for arguments sake that Anderson et al. is deemed analogous art, it is respectfully submitted that the combination of Dietz, Rienmueller et al. and Anderson et al. under 35 U.S.C. § 103 is improper, because of a lack of motivation to do so. In particular, claim 15 recites "an abort switch adapted to halt the apparatus for administering radiation therapy and open a closed one of the first and second selectively operable valves." The Final Office Action has conceded that both Dietz and Rienmueller et al. do not disclose the recited abort switch. Anderson et al. does not solve the deficiencies of Dietz and Rienmueller et al. in that Anderson et al. is directed

to an apparatus for delivering ultraviolet radiation to discrete areas of a patient's skin. Anderson et al. is completely unrelated to any type of suspension of breathing during radiation therapy (see, for example, Figures 1 and 2). It is noted that the Final Office Action has relied on a "kill-switch" mentioned at column 12, lines 3-5 of Anderson et al. as providing motivation to use the recited abort switch in Dietz "to allow termination of radiation therapy if the correct parameters are not optimum (col. 13, lines 58-63)." However, Anderson et al.'s "kill-switch" only performs the function of closing shutter 36 and terminating "delivery of therapeutic doses of radiation to the patient." (Col. 12, II. 3-5). Anderson et al. fails to have the "kill-switch" also open a closed valve that is adapted to either control inhalation or exhalation of the patient in the manner recited in claim 15. Furthermore, Anderson et al.'s shutter 36 that is controlled by the "kill-switch" cannot properly be viewed as a valve adapted to control inhalation and/or exhalation of a patient. Rather, as expressly described by Anderson et al., the shutter 36 simply controls transmission of radiation to the skin of a patient by positioning "the screen to block the beams, or pass the beams through one of the apertures." (Col. 11, II. 14-16). It is noted that the Final Office Action asserts that "Dietz/Rienmueller is fully capable of performing the same function" based on col. 4, lines 1-5 of Rienmueller et al. The passage states:

When possible, the patient 4 may hold the spirometer 8 himself, and may thus actively interrupt the examination at any time if shortness of breath occurs. The brief interruption of the respiratory flow therefore does not present a risk to the patient.

The above passage merely suggests that when the patient has shortness of breath, he or she removes the spirometer 8 from his or her mouth to enable improved breathing and the radiologist does not activate the x-ray imager while the spirometer 8

is removed. The above process in no way discloses or suggests claim 15's abort switch. Since there is no motivation to combine Anderson et al. with either Dietz or Rienmueller et al. in the manner suggested by the Final Office Action, the rejection is improper and should be withdrawn.

It is noted that the Advisory Action mailed on June 24, 2005 has made reference to the case *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) for the proposition that the courts do not require motivation to combine references to be expressly articulated. Appellants will take that as a concession that the references do not explicitly suggest the combination suggested by the rejection. Furthermore, it should be noted that the court in *In re McLaughlin* based its decision by finding that the secondary references of the rejection provided the necessary suggestion to combine the references. *Id.* at 1395, 170 USPQ at 212.²

b. Claims 29 and 31

Claims 29 and 31 were finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al. and Anderson et al.

Appellants traverse the rejection of claim 29 for several reasons. First, claim 29 depends directly on claim 15 and so is patentable over Dietz, Rienmueller et al. and

² The Advisory Action has also relied on the case *In re Bozek*, 416 F.2d 1385, 163 USPQ 545 (CCPA 1969) for its assertion that "references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures." If the assertion is that express disclosures of a reference can be ignored, then it is incorrect. The express disclosures of a reference must be considered along with what the reference fairly suggests. *In re Baird*, 16 F.3d 380, 383, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). It appears that the assertion is based on the *In re Bozek* court's statement that "a reference disclosure must be evaluated for *all* that it fairly suggests and not only for what is indicated as preferred" (emphasis as in original). *In re Bozek*, 416 F.2d at 1390, 163 USPQ at 549. The statement clearly means that the teachings of a reference are not limited to the preferred embodiment.

Anderson et al. for at least the same reasons given above in Section VII.B.1.a. as to why claim 15 is patentable over the references.

It is noted that the Final Office Action refers to U.S. Patents Nos. 5,111,809; 5,479,920 and 6,571,796 as ventilators using two one-way valves. However, the rejection at page 3 of the Final Office Action only refers to Dietz, Rienmueller et al. and Anderson et al. as being relied on to reject the claims. Appellants requested clarification of this rejection in their Amendment filed on May 9, 2005. Unfortunately, the Advisory Action mailed on June 24, 2005 provided no such clarification. Accordingly, Appellants request clarification in the Examiner's Answer.

Even if the above-mentioned three patents were combined with Dietz,
Rienmueller et al. and Anderson et al. they would not overcome the improperness of the
rejection. First, U.S. Patent No. 6,571,796 does not qualify as prior art. Second, the
remaining two patents do not suggest using the recited abort switch in either Dietz,
Rienmueller et al. or Anderson et al.

For the above reasons, the rejection of claim 29 is improper and should be withdrawn.

Claim 31 depends directly on claim 29 and so its rejection should be withdrawn for the same reasons stated above with respect to claim 29.

c. Claim 30

Claims 30 was finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al. and Anderson et al. Appellants traverse the rejection for several reasons. First, claim 30 depends directly on claim 15 and so is patentable over Dietz, Rienmueller et al. and Anderson et al. for at least the

same reasons given above in Section VII.B.1.a. as to why claim 15 is patentable over the references.

It is noted that the Final Office Action refers to U.S. Patents Nos. 5,111,809; 5,479,920 and 6,571,796 as ventilators using two one-way valves. For the same reasons given above in Section VII.B.1.b Appellants request clarification in the Examiner's Answer as to whether the references are being used in the rejection of claim 30.

Even if the above-mentioned three patents were combined with Dietz,
Rienmueller et al. and Anderson et al. they would not overcome the improperness of the
rejection for the same reasons given above in Section VII.B.1.b.

For the above reasons, the rejection of claim 30 is improper and should be withdrawn.

d. Claim 33

Claim 33 was finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al. and Anderson et al. Appellants traverse the rejection for several reasons. First, as shown above in Section VII.B.1.a., Anderson et al. is directed to nonanalogous art. Second, claim 33 recites "an abort switch adapted to halt the apparatus for administering radiation therapy and open the selectively operable valve." For reasons similar to those given above in Section VII.B.1.a with respect to claim 15, there is no motivation to combine Anderson et al. with Dietz and Rienmueller et al. in the manner suggested by the Final Office Action since Anderson et al. fails to have its "kill-switch" also open a selectively operable valve that is

adapted to control both inhalation and exhalation of the patient as recited in claim 33.

Accordingly, the rejection is improper and should be withdrawn.

2. Dietz, Rienmueller et al., Anderson et al. and Beran

a. Claims 23-26

Claims 23-26 were was finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al., Anderson et al. and Beran. Appellants traverse the rejection for several reasons. In particular, regarding claim 23 it depends directly on claim 15. Accordingly, the rejection is improper since Anderson et al. is directed to non-analogous art as mentioned previously in Section VII.B.1.a. In addition, Dietz, Rienmueller et al. and Anderson et al. do not suggest using an abort switch that also opens a closed valve that is adapted to either control inhalation or exhalation of the patient as mentioned above in Section VII.B.1.a. Since Beran does not suggest using an abort switch that also opens a closed valve that is adapted to either control inhalation or exhalation of the patient as recited in claim 15, the rejection of claim 23 is improper and should be withdrawn.

Claims 24-26 depend directly or indirectly on claim 23 and so their rejections should be withdrawn for the same reasons stated above with respect to claim 23.

b. Claims 34-36

Claims 34-36 were was finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al., Anderson et al. and Beran. Regarding claim 34 it depends directly on claim 33. Accordingly, the rejection is improper since Anderson et al. is directed to non-analogous art as mentioned previously in Section VII.B.1.d. In addition, Dietz, Rienmueller et al. and Anderson et al. do not

suggest using an abort switch that also opens a selectively operable valve. For reasons similar to those given above in Section VII,B.1.d with respect to claim 33, there is no motivation to combine Anderson et al. with Dietz and Rienmueller et al. in the manner suggested by the Office Action since Anderson et al. fails to have its "kill-switch" also open a selectively operable valve that is adapted to control both inhalation and exhalation of the patient. Since Beran does not suggest using an abort switch that also opens a selectively operable valve that is adapted to control both inhalation and exhalation of the patient as recited in claim 33, the rejection of claim 34 is improper and should be withdrawn.

Claims 35 and 36 depend directly or indirectly on claim 34 and so their rejections should be withdrawn for the same reasons stated above with respect to claim 34.

3. Dietz, Rienmueller et al., Anderson et al. and Voss

a. Claim 27

Claim 27 was finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al., Anderson et al. and Voss. Claim 27 depends indirectly on claim 15. Accordingly, the rejection is improper since Anderson et al. is directed to non-analogous art as stated previously in Section VII.B.1.a. In addition, Dietz, Rienmueller et al. and Anderson et al. do not suggest using an abort switch that also opens a closed valve that is adapted to either control inhalation or exhalation of the patient as mentioned in Section VII.B.1.a. Since Voss does not suggest using an abort switch that also opens a closed valve that is adapted to either control inhalation or exhalation of the patient as recited in claim 15, the rejection is improper and should be withdrawn.

The rejection of claim 27 is improper for the additional reason that there is no motivation to have a display attached to the mirror. Since there is no motivation in Voss or the other cited art to attach a display to the mirror of Voss, the rejection should be withdrawn.

b. <u>Claim 28</u>

Claims 28 was finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al., Anderson et al. and Voss. Claim 28 depends directly on claim 15. Accordingly, the rejection is improper since Anderson et al. is directed to non-analogous art. In addition, Dietz, Rienmueller et al. and Anderson et al. do not suggest using an abort switch that also opens a closed valve that is adapted to either control inhalation or exhalation of the patient as mentioned in Section VII. B.1.a. Since Voss does not suggest using an abort switch that also opens a closed valve that is adapted to either control inhalation or exhalation of the patient as recited in claim 15, the rejection is improper and should be withdrawn.

c. Claim 37

Claim 37 was finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al., Anderson et al. and Voss. Claim 37 depends indirectly on claim 33. Accordingly, the rejection is improper since Anderson et al. is directed to non-analogous art as stated previously in Section VII.B.1.d. In addition, Dietz, Rienmueller et al. and Anderson et al. do not suggest using an abort switch that also opens a selectively operable valve. For reasons similar to those given above in Section VII.B.1.d with respect to claim 33, there is no motivation to combine Anderson et al. with Dietz and Rienmueller et al. in the manner suggested by

the Final Office Action since Anderson et al. fails to have its "kill-switch" also open a selectively operable valve that is adapted to control both inhalation and exhalation of the patient. Since Voss does not suggest using an abort switch that also opens a selectively operable valve that is adapted to control both inhalation and exhalation of the patient as recited in claim 33, the rejection is improper and should be withdrawn.

The rejection of claim 37 is improper for the additional reason that there is no motivation to have a display attached to the mirror. Since there is no motivation in Voss or the other cited art to attach a display to the mirror of Voss, the rejection should be withdrawn.

d. <u>Claim 38</u>

Claim 38 was finally rejected in the Final Office Action under 35 U.S.C. §103(a) as being obvious in view of Dietz, Rienmueller et al., Anderson et al. and Voss. Claim 37 depends directly on claim 33. Accordingly, the rejection is improper since Anderson et al. is directed to non-analogous art as stated in Section VII.B.1.d. In addition, Dietz, Rienmueller et al. and Anderson et al. do not suggest using an abort switch that also opens selectively operable valve." For reasons similar to those given above in Section VII.B.1.d with respect to claim 33, there is no motivation to combine Anderson et al. with Dietz and Rienmueller et al. in the manner suggested by the Office Action since Anderson et al. fails to have its "kill-switch" also open a selectively operable valve that is adapted to control both inhalation and exhalation of the patient. Since Voss does not suggest using an abort switch that also opens a selectively operable valve that is adapted to control both inhalation and exhalation of the patient as recited in claim 33, the rejection is improper and should be withdrawn.

For the reasons give above, Appellants respectfully submit that the rejections should be withdrawn and the claims should be allowed.

Respectfully submitted,

John C. Freeman

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Dated: September 8, 2005

VIII. CLAIMS APPENDIX

15. An apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation, the apparatus comprising:

an apparatus for identifying a specific air flow direction and lung volume of the patient;

an apparatus for suspending patient ventilation at the specific air flow direction and lung volume, the apparatus for suspending patient ventilation including a ventilator assembly having a first selectively operable valve adapted to control inhalation of the patient and a second selectively operable valve adapted to control exhalation of the patient;

an apparatus for administering radiation therapy during the suspension of patient ventilation; and

an abort switch adapted to halt the apparatus for administering radiation therapy and open a closed one of the first and second selectively operable valves.

- 23. The apparatus of claim 15, wherein the ventilator assembly comprises a t-connector that includes the first selectively operable valve, the second selectively operable valve and a pneumotach.
- 24. The apparatus of claim 23, further comprising a computer that is operably associated with the ventilator assembly.
 - 25. The apparatus of claim 24, further comprising:a first valve in fluid communication with the first selectively operable valve

and operably associated with the computer;

a second valve in fluid communication with the second selectively operable valve and operably associated with the computer; and wherein the pneumotach is operably associated with the computer.

- 26. The apparatus of claim 24, further comprising a display operably associated with the computer so that the display provides a readout of a cyclical lung volume trace and a target respiration level while the patient is breathing.
- 27. The apparatus of claim 26, further comprising a mirror for viewing a face of the patient, wherein the display is attached to the mirror.
- 28. The apparatus of claim 15, further comprising a mirror for viewing a face of the patient.
- 29. The apparatus of claim 15, wherein the first selectively operable valve is a one-way valve.
- 30. The apparatus of claim 15, wherein the second selectively operable valve is a one-way valve.
- 31. The apparatus of claim 29, wherein the second selectively operable valve is a one-way valve.

- 32. The apparatus of claim 15, further comprising a mouthpiece attached to the ventilator assembly.
- 33. An apparatus for suspending ventilation in a patient and delivering radiation therapy to the patient during suspended ventilation, the apparatus comprising:

an apparatus for identifying a specific air flow direction and lung volume of the patient;

an apparatus for suspending patient ventilation at the specific air flow direction and lung volume, the apparatus for suspending patient ventilation including a ventilator assembly having a selectively operable valve adapted to control both inhalation and exhalation of the patient;

an apparatus for administering radiation therapy during the suspension of patient ventilation; and

an abort switch adapted to halt the apparatus for administering radiation therapy and open the selectively operable valve.

- 34. The apparatus of claim 33, wherein the ventilator assembly comprises a pneumotach.
- 35. The apparatus of claim 34, further comprising a computer that is operably associated with the selectively operable valve and the pneumotach.
- 36. The apparatus of claim 35, further comprising a display operably associated with the computer so that the display provides a readout of a cyclical lung

volume trace and a target respiration level while the patient is breathing.

- 37. The apparatus of claim 36, further comprising a mirror for viewing a face of the patient, wherein the display is attached to the mirror.
- 38. The apparatus of claim 33, further comprising a mirror for viewing a face of the patient.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.



09-09.05

U.S.P.S. EXPRESS MAIL "POST OFFICE TO ADDRESSEE" SERVICE DEPOSIT INFORMATION

Express Mail Label No.: EV 653 877 034 US

Date of Deposit: September 8, 2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re	Appln. of:	John V	V. Woi	ng et al.								
Appli	n. No.: 09/424,431							Examiner: Michael G. Mendoz				
Filed	d: March 16, 2000							Art Un	it:	3731		
For:	·						ı					
Attor	ney Docke	t No:	1054	6/6								
Comn P. O. Alexa	Stop Appeal E nissioner for Box 1450 ndria, VA 22	Patents					T	RANSI	/IIT	TAL		
Sir:												
\boxtimes	Return Reco alculation: No addition: Small Entity An extensio A petition or	eipt Posto al fee is re n fee in a	ard equired. n amoui	nt of \$ for a _ nan amount of \$ een calculated as st	mon under	th 37	extensio	n of time ur		37 C.F.R.	§ 1.136(a).	
	•	5					Sma	mall Entity		Not a S	mall Entity	
	Claims Re			Highest No. Previously Paid For	Present Extra		Rate	Add'l Fee	or	Rate	Add'i Fee	
Total			Minus				x \$25=			x \$50=		
Indep.			Minus			_	X100=		<u> </u>	x \$200=		
First Presentation of Multiple Dep. Claim +\$18						+\$180=			+ \$360=			
							Total	\$		Total	\$	
-	Please char enclosed fo Payment by The Directo § 1.16 and (including a	ge Depos r this purp r credit ca r is hereb any pate any exter	sit Accou loose. In the loy autho lent applosion fe	20 is enclosed. unt No. 23-1925 in the amount of \$ prized to charge paylication processing the required to encount No. 23-1925.	(Form PT yment of a fees und	O- any er	2038 is a a addition 37 CFR	al filing fee § 1.17 as	s rec	quired un ated with	der 37 CFR	
	Respectfylly s											

Date Ptember 8, 2065

John C. Freeman (Reg. No. 34,483)